

between the lines

Dr Darrin Baines

Flood warning

With the European Commission opening the floodgates, is this the beginning of DTC?

It pays to be direct. Straight talking makes the world a better place; friendships improved, marriages saved and arguments ended just through both sides speaking their minds.

Direct communication not only improves relationships but can save lives. If healthcare professionals have the right information at the right time their choices of patient care become more appropriate, more effective and safer.

Similarly, if patients are fully informed the way they access health services can improve, they can become more rational. Indeed, you'd think that when directness obviously pays we'd all automatically be given any medical information that affects the quality of our lives. Sadly not. As far as medical information is concerned, UK patients are kept in the dark and only fed what legislators feel they can safely digest. However, the situation may soon change.

On 18 July, the European Commission adopted proposals for comprehensive reform of EU pharmaceutical legislation including proposals for more and better information on prescription medicines for patients. The aim being to provide "valid, patient-orientated information" to all European patients.

The EC review of pharmaceutical legislation was based upon two fundamental objectives: the need to guarantee a high level of health protection for European citizen, and completion of the internal market for pharmaceutical products.

Despite their importance, not all consumer groups are happy with the proposed changes. In a recent report, the Consumers' Association (CA), using US evidence, argued that: "Much of the information provided by pharmaceutical companies [directly to patients] is neither empowering nor complete."

The Association is not against knowledgeable health service users, it simply suggests: "the critical question is whether advertising is the type of communication that can contribute to the development of informed and empowered patients."

Using logical arguments and US experience, the Association concludes that the Europe-wide ban on direct-to-consumer (DTC) advertising should not be lifted. It seems some straight talking about being direct with patients is now needed.

The European Commission proposals also see a streamlining of the drug approval process by cutting red tape,



thereby benefiting patients by bringing new medicines to market sooner, while increasing the competitiveness of European pharma industry.

In response to the shift of clinical research to the US, the Commission proposes to bring Europe closer to the US regulatory environment, and that means DTC.

The ban on DTC has seemed untenable for many people for a while, mainly due to information access via the internet. In fact it has created inequalities between online and offline consumers. The Commission is facing up to the situation and improving the flow of information to patients.

This is not a prospect that fills doctors or consumer groups with confidence. In America, spending on drugs rose by \$42.7 billion (£30.5 billion) in the five years from 1993 when DTCA started to gather speed.

This is an astronomical rise of 84 per cent, nearly a fifth of which was due to the most heavily advertised drugs. Nice for pharma but the NHS clearly would be unable to bear such costs.

In a new report entitled, *Promotion of prescription drugs: public health or private profit?* (available at www.which.net), the CA cites the US experience as a warning of the implications of DTC. ►►

between the lines

► In response, they have called upon the Government to urgently consider the full implications of a shift in policy towards DTC promotion. Report editor, Clara Mackay: "The critical question is whether advertising is the type of communication that can contribute to the development of informed and empowered patients."

Based upon US data, the Association believes it is not. They cited a study that found fewer than half of 28 US drug adverts analysed were honest about efficacy and described benefits and risks fairly in the main text. Moreover, the Association found that the FDA warned the makers of one coronary heart disease drug that their broadcast advertisements made false claims about efficacy, provided inadequate information, and made misleading claims about costs.

The Consumers' Association advocates a database system of information where literature could be submitted by drug companies but is assessed independently.

In the UK, the ABPI has been leading the debate on internet access to medicines information and, with the caricature of big, nasty pharma manipulating helpless patients for massive profits often being employed by sides against DTCA, the ABPI represents a sensible voice.

In its position paper on pharmaceuticals and the internet published in October 2000, the ABPI proposed that pharma should be allowed to educate and freely

inform consumers on the best use of its own products and correct the information imbalance created by the net.

Commenting on this paper, Richard Ley, press officer at the ABPI, said: "We are pushing for the possibility of giving patients more information."

There are two major drivers for change: the patients, who want more information on their treatment than they used to, and the development of the Internet, where patients can access hundreds of sites about drugs produced around the world, but don't know what's reliable."

With such a confusion of information available, Ley argued: "It would be good for patients to be able to turn to what the manufacturers say."

However, an important safeguard would be the regulation of drug information sheets or web pages under a specially devised Code of Practice. "At this stage we aren't talking about advertising," but with the correct regulations in place, Richard Ley believes "anything is possible in the future."

In the debate on DTCA, straight talking is required. By speaking their minds, it seems the various sides in the debate are finding a common voice.

Firstly, any sensible person would agree that the worst excess of DTCA should not be imported from the US into the UK. Second, all sides favour sensible regulation,

which should be relaxed as European evidence on DTCA is amassed.

Finally, it seems some form of independent regulatory body is required, which analyses the promotional materials produced and sets guidelines.

Given its experience of devising and policing the UK code of practice for advertising, the ABPI seems to be the body best positioned for this task.

In my mind, the ABPI's position on information provision, with greater access improving decision-making and reducing inequalities, seems indubitably sound.

Not only should we have faith in their position because its is sensible, workable and safe but because the ABPI is not in favour of the worst excesses of DTCA seen in America at present.

It may be time to stop debating, to join together and to ask the ABPI to speak for pharma on this issue with its sensible, reliable voice.

Whilst only a tentative step in a new direction, this move clearly revives the flagging debate on direct to consumer promotion.

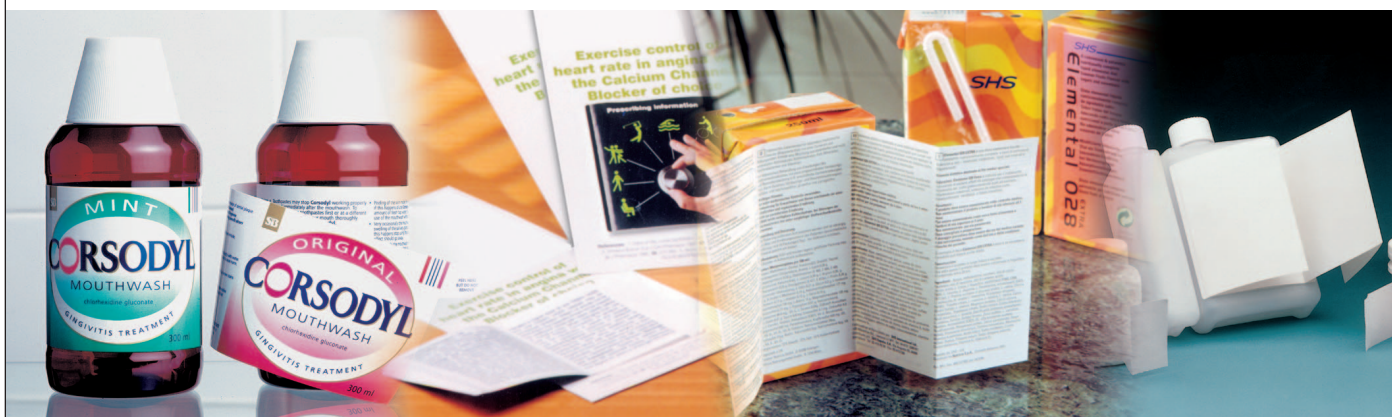
The EC proposals might not be a watershed but the flood gates are open. Or has the European dam against the pressure of DTC sprung a leak?

THE AUTHOR

Dr Darrin Baines is director of medM Limited.
He can be contacted at: info@medm.co.uk

Pharmaceutical / fap. 1. satisfy legal requirements
2. inform, educate end user 3. product authenticity
4. reduce packaging costs (multi lingual, no carton)
5. quality accredited ISO9002, 6. security 7. variety of formats to suit styles of information i.e. barcodes, diagrams, illustrations, over coding

Fix - a - Form - communication defined



secure and user friendly health education multi-lingual text dosage and user information



Denny Bros Ltd

Kempson Way, Bury St. Edmunds, Suffolk IP32 7AR
Tel 01284 701381, Fax 01284 705575
e-mail: fix-a-form@dennybros.com www.dennybros.com